

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK

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NATALIE TILLET,

Plaintiff,

DECISION AND ORDER

v.

Case # 6:23-cv-06031-FPG

COOPERSURGICAL, INC.,  
FEMCARE, LTD. – UK SUBSIDIARY OF  
UTAH MEDICAL PRODUCTS, INC., and  
UTAH MEDICAL PRODUCTS, INC.

Defendants.

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**INTRODUCTION**

Plaintiff, Natalie Tillet (“Plaintiff”), brings this diversity action against CooperSurgical, Inc., Utah Medical Products, Inc., and Femcare, Ltd. (collectively “Defendants”). She seeks compensation for injuries allegedly caused by a migrating Filshie Clip, a medical device used in tubal ligations, which is a form of birth control. ECF No. 1. Defendants have moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Plaintiff’s state-law claims are preempted, and to the extent they are not preempted, fail to state a claim upon which relief can be granted. ECF Nos. 10, 20, 25. For the reasons that follow, Defendants’ motions to dismiss are GRANTED.

**BACKGROUND**

For the purpose of ruling on the motions to dismiss, the Court accepts as true all well-pleaded allegations in the complaint and draws all reasonable inferences in Plaintiff’s favor, as summarized below.

In 2017, Plaintiff underwent a tubal ligation procedure to implant a Filshie Clip on her fallopian tubes. ECF No. 1 ¶ 60-62. In August 2021, Plaintiff began noticing signs of discomfort and pain in the area where the Filshie Clip had been implanted. ECF No. 15 at 27. Plaintiff also

began to experience very heavy menstrual cycles with clotting, constant severe abdominal pain, severe weight gain, and thinning hair. ECF No. 1 ¶ 64. By April 2022, Plaintiff's symptoms worsened to the point that she went to the Emergency Department at Rochester Regional Health, where she complained of right-side flank pain radiating around the front. *Id.* ¶ 66. It was later discovered that the cause of Plaintiff's pain was the Filshie Clip, which had migrated from its original location to the upper and anterior to the transverse colon. *Id.* ¶ 67. Plaintiff's doctors attempted to surgically remove the Filshie Clip, first on May 16, 2022 and then again on July 6, 2022, however, both attempts to remove the Filshie Clip were unsuccessful. *Id.* Plaintiff continues to live with the pain and discomfort alleged to have been caused by the migrated Filshie Clip. *Id.* ¶ 68.

On January 13, 2023, Plaintiff filed the instant action asserting state-law claims sounding in negligence and strict liability for design defect, manufacturing defect and failure to warn. Plaintiff also asserts claims under Sections 349 and 350 of New York's General Business Law ("NYGBL"). Plaintiff asserts her state-law claims "only to the extent that they are parallel to and not different from or in addition to the requirements of federal law." ECF No. 1 ¶ 27.

### **STANDARD OF REVIEW**

When ruling on a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 128 (2d Cir. 2011). However, the Court is not required to credit legal conclusions, bare assertions, or conclusory allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 681, 686 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter ... to 'state a claim to relief that is plausible on its face.'" *Id.* at 678 (quoting

*Twombly*, 550 U.S. at 570). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). The plaintiff must allege sufficient facts to show “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* If the plaintiff has not “nudged [her] claims . . . across the line from conceivable to plausible,” the complaint must be dismissed. *Id.* at 680 (quoting *Twombly*, 550 U.S. at 570).

## DISCUSSION

Defendants argue, *inter alia*, that all of Plaintiff’s claims are preempted or otherwise fail to state a claim for relief. The Court agrees. Utah Medical Products, Inc. and Femcare, Ltd. also object to this Court’s exercise of personal jurisdiction over them, however, given the Court’s conclusion under Rule 12(b)(6), it need not address those arguments. *See, e.g., Chevron Corp. v. Naranjo*, 667 F.3d 232, 246 n.17 (2d Cir. 2012). If Plaintiff files an amended complaint, Defendants are free to renew those arguments or incorporate them by reference in any future motion.

### I. Federal Preemption

State-law product liability claims relating to the safety or effectiveness of a Class III<sup>1</sup> medical device have a narrow gap through which they must fit in order to escape express or implied preemption. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). On the one hand, such claims are expressly preempted if they are “different from, or in addition to, any requirement applicable” to the device under the Medical Device Amendments

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<sup>1</sup> Under the Medical Device Amendments (“MDA”), medical devices are organized into classes based on the amount of federal oversight they receive. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 328 (2008) A device is assigned to Class III if “there are not any less stringent classifications which would reasonably assure the device’s safety and effectiveness, and the device is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.” *Id.* at 317.

(“MDA”) to the Food, Drug, and Cosmetic Act (“FDCA”). 21 U.S.C. § 360k(a); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (“State requirements are pre-empted under the MDA only to the extent that they are different from, or in addition to the requirements imposed by federal law.”). Express preemption, however, does not “bar a state from providing a damages remedy for claims premised on the violation of FDA regulations, because the state duties in such a case parallel, rather than add to, federal requirements.” *Riegel*, 552 U.S. at 330. On the other hand, state-law tort claims are “impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA rather than on some independent state law duty.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001). In other words, in order to avoid express or implied preemption, the plaintiff’s state-law claim must “parallel a federal-law duty under the MDA but also exist independently of the MDA.” *A.F. By & Through Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018).

All parties agree that the Filshie Clip is a Class III medical device and is, therefore, subject to the MDA. *See generally* ECF Nos. 1, 10, 20, 25. Accordingly, state-law tort claims relating to the safety and effectiveness of the Filshie Clip, such as Plaintiff’s claims for design defect, manufacturing defect and failure to warn, are subject to the foregoing federal preemption regime.

#### **A. Design Defect**

Plaintiff’s claim for design defect falls squarely within the express preemption provision of the MDA. *See Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013) (citing *Riegel* for the proposition that “design defect claims regarding a PMA-approved device are squarely preempted by the MDA”).

In conditionally approving the Filshie Clip, the FDA approved a specific design that it believed was reasonably safe and effective to use. A design defect claim, however, requires

asserting that it was feasible to design the Filshie Clip in a safer manner, *i.e.*, even more safely than as approved by the FDA. *See Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013) (noting that, to state a claim for design defect, a plaintiff must allege that “(1) the product as designed posed a substantial likelihood of harm; (2) *it was feasible to design the product in a safer manner*; and (3) the defective design was a substantial factor in causing plaintiff’s injury” (emphasis added)). Therefore, a design defect cause of action would impose additional requirements on the FDA-approved device that exceeds the safety requirements of the FDA. These additional state requirements are necessarily different from federal law, and accordingly, the design defect claim is preempted under the MDA. *See Riegel*, 552 U.S. at 330.

## **B. Manufacturing Defect**

To plead a claim for a manufacturing defect, the plaintiff must show that a specific product unit was defective as a result of “some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,” and that the defect was the cause of plaintiff’s injury.” *A.F. v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 542 (S.D.N.Y. 2018). “In other words, a manufacturing flaw exists when the unit in question deviates in quality and other performance standards from all of the other identical units.” *Id.*

A claim for a manufacturing defect that deviates from the design approved and required by the FDA is “parallel” to and not preempted by 21 U.S.C. § 360k(a). *See Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) (“[C]laims for defective manufacture in violation of federal law are not expressly preempted by section 360k.”); *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 155–56 (S.D.N.Y. 2011) (holding that manufacturing defect claims alleging that a device was not manufactured in accordance with FDA requirements are not preempted).

Here, however, Plaintiff has failed to plausibly allege a manufacturing defect that violated FDA requirements. Plaintiff vaguely alleges that the “[d]efendants did not adequately adhere to the conditions of approval and post approval requirements that are expected to be in the PMA approval order” and that the Filshie Clip attached to her fallopian tube “contained a condition or conditions at the time the Filshie Clips left Defendants’ control.” ECF No. 1 ¶¶ 59(1), 95. Plaintiff’s vague and generic assertions are insufficient to plausibly allege a manufacturing defect because they do not identify or otherwise explain the specific “conditions” that allegedly deviated from the approved product design.

Plaintiff argues that because the premarket approval documents are confidential, “formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim” in the context of Class III medical devices. ECF No. 1 ¶ 27 n.1 (citing *Bausch*, 630 F.3d at 560). However, Plaintiff’s reliance on *Bausch* is misplaced. In *Bausch*, the plaintiff alleged that the medical device at issue suffered “dimensional anomalies,” but failed to allege how those dimensional anomalies deviated from the FDA approved design. *See Bausch*, 630 F.3d at 559. The court determined that formal discovery would be necessary to fill in the gap between the plaintiff’s theory of the alleged defects—dimensional anomalies—and the FDA approved design. *See Id.* at 558.

Here, Plaintiff has not even alleged a defect. Rather, Plaintiff has merely asserted *something was defective*, and no amount of discovery can help fill in the gap because Plaintiff does not have a working theory of what she would be seeking to discover. Accordingly, Plaintiff has failed to plausibly allege a manufacturing-defect claim and the claim must be dismissed. *Accord A.F.*, 346 F. Supp. 3d at 542 (dismissing a complaint of manufacturing defect on the basis that plaintiff’s claims were conclusory and did not contain sufficient factual specificity); *Horowitz v. Stryker*

*Corp.*, 613 F. Supp. 2d 271, 283 (E.D.N.Y. 2009) (finding that although “[t]he complaint contains a few generic allegations of a manufacturing defect, these allegations do not . . . suggest that the particular alleged failure is a failure to manufacture the device in accordance with federal standards”).

### **C. Failure to Warn**

Plaintiff next alleges that Defendants failed to warn of the dangers of the migrating Filshie Clip and that such failure to warn caused her injuries. ECF No. 1 ¶ 49-52. Specifically, Plaintiff alleges that “Defendants neither warned nor adequately informed . . . her healthcare providers how frequently these migrations occur or the severity and permanency of the potential injuries,” ECF No. 1 ¶ 49, and that “Plaintiff suffered as a result of Defendants’ failure.” *Id.* Defendants argue that Plaintiff’s claim is preempted by federal law because it is “different from and in addition to” the MDA requirements. ECF No. 10-4 at 15; *see also* 21 U.S.C. § 360k.

The MDA imposes an ongoing obligation on medical device manufactures to submit adverse event reports to the FDA consisting of information “that reasonably suggests that a device . . . may have caused or contributed to a death or serious injury.” 21 C.F.R. § 803.50. Simultaneously, under New York law, medical device manufacturers have a duty to warn patients of potential adverse side effects of medical devices. *Banker v. Hoehn*, 278 A.D.2d 720, 721 (3d Dep’t 2000). The question is whether the duty to warn patients under New York law is “parallel” to the duty to report adverse events to the FDA.

The duty to warn under New York law is “different from and in addition to” the duty to supply adverse event reports to the FDA because the duty under New York law runs to the patient. While a medical device manufacturer can satisfy this duty under New York law by adequately warning a “learned intermediary,” the FDA is not a learned intermediary for this purpose. *See*

*Banker*, 278 A.D.2d at 721. A learned intermediary is a “medical professional[] who use[s] the device *in the treatment of patients*.” *Id.* (emphasis added). Warning the “learned intermediary” can satisfy the duty to warn patients because “learned intermediaries” are expected, indeed they have a duty, “to balance the risks against the benefits of various . . . treatments and to prescribe them and supervise their effects.” *Martin v. Hacker*, 83 N.Y.2d 1, 9 (1993); *see also Bukowski v. CooperVision Inc.*, 185 A.D.2d 31, 35 (3d Dep’t 1993) (stating that a learned intermediary is “a medical professional with the knowledge and expertise to assimilate technical information” and is expected “to assess the risks and benefits posed by the drug or device in light of the particular patient’s medical history and treatment needs”). The FDA does not treat patients. The FDA does not prescribe and supervise the effects of various treatments. While the FDA does balance the risks and benefits of a particular device when deciding whether to grant premarket approval for a particular device, this is a generalized determination and not one done “in light of the particular patient’s medical history and treatment needs.” *Bukowski*, 185 A.D.2d at 35.

Furthermore, Plaintiff cannot argue that submitting a report to the FDA is an adequate method of warning learned intermediaries of potential dangers, because there is no “reasonable assurance that the information will reach those whose safety depends upon their having it.” *Restatement (Second) of Torts* § 388 cmt. n (1965). When adverse events are reported to the FDA, there is no reasonable assurance that the information will be disseminated to the appropriate professional with the treating relationship to the patient because the FDA is not required to publicly release such reports. *See* 21 C.F.R. § 803.9(a) (stating that the FDA “*may* disclose to the public any [adverse event] report” (emphasis added)). Moreover, when the FDA exercises its discretion to release adverse event reports publicly, it does so only passively by uploading the reports to an online database. *See MAUDE-Manufacturer and User Facility Device Experience*, FDA,

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> (last updated 05/31/2023) (“Although MDRs are a valuable source of information, this *passive surveillance system* has limitations . . .”). Accordingly, in order to satisfy their duty to warn patients of potential adverse side effects of medical devices through a learned intermediary, Defendants would need to do more than they are required to do under the MDA. Therefore, a failure to warn claim under New York law is “different from and in addition to” their duty to supply adverse event reports to the FDA is preempted under *Riegel*. *Riegel*, 552 U.S. at 330.

Plaintiff urges this Court to rely on the ruling in *Rosen v. St. Jude Medical, Inc.*, 41 F. Supp. 3d 170 (N.D.N.Y. 2014). There the district court found that “a cause of action [could] exist under this duty [to warn] where a manufacturer fails to report complaints to the FDA about a device.” *Id.* at 184. However, that ruling is in direct conflict with New York law as discussed, *supra*, and this Court is not bound by that outcome.

Plaintiff further argues the Second Circuit’s decision in *Glover v. Bausch & Lomb Inc.*, 43 F.4th 304 (2d Cir. 2022), requires a different outcome. However, *Glover* is inapposite because that case involved the application of Connecticut law while this case requires the application of New York law. Moreover, the Connecticut law at issue in *Glover* was statutory and broader in its scope than New York’s common-law failure to warn claim, which ties the duty to a “learned intermediary” who has a duty to balance the risks and benefits for that particular patient.

Plaintiff also attempts to articulate her claim as one arising directly from the MDA by stating that “Defendants had received adverse reports” of the increased risk of migration, but that such increased risk “was not reported to the FDA.” ECF No. 1 ¶¶ 49, 86. However, this method of bringing the claim falls squarely within the implied preemption doctrine. *Buckman*, 531 U.S. at 352, 353 (“Congress intended that the MDA be enforced exclusively by the Federal Government,”

and thus a state law claim that exists “solely from the violation of [federal] requirements” is impliedly preempted.).

#### **D. Negligence and Gross Negligence**

Plaintiff also articulates her claims for design defect, manufacturing defect and failure to warn as a negligence claim and alleges that Defendant’s actions were grossly negligent. *See* ECF No. 1 ¶¶ 129, 164. However, because strict product liability and negligence claims are essentially the same under New York law, plaintiff’s claims for design defect, manufacturing defect and failure to warn claims are dismissed for the same reasons previously articulated. *See S.F. v. Archer Daniels Midland Co.*, 594 F. App’x 11, 12 (2d Cir. 2014) (summary order) (“New York courts generally consider strict products liability and negligence claims to be functionally synonymous.”).

#### **E. New York General Business Law**

Next, Plaintiff brings a claim alleging a violation of the New York Unfair Trade Practices Act. Section 349 of the New York’s General Business Law (“NYGBL”) proscribes “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service” in New York. N.Y. Gen. Bus. Law § 349(a). To state a claim under NYGBL § 349, “a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice.” *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (*quoting Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 944 (2012)). Section 350 of the NYGBL proscribes “[f]alse advertising in the conduct of any business, trade or commerce.” N.Y. Gen. Bus. Law § 350. To establish a false advertising claim under § 350, “[a] plaintiff must demonstrate that the advertisement (1) had an impact on consumers at large, (2) was deceptive or misleading in a material way, and (3) resulted in injury.” *Andre Strishak & Assocs., P.C. v. Hewlett Packard Co.*,

300 A.D.2d 608, 609 (2d Dep’t 2002). Under Section 350, a plaintiff must plead reliance on a false advertisement at the time the product was purchased. *Id.* at 610.

Plaintiff has alleged that Defendants engaged in “consumer-oriented conduct” regarding the Filshie Clip by stating that “Defendants told women they could use Filshie Clips to effectively prevent pregnancy while the product was in place and that the product was safe.” ECF No. 1 ¶ 42. However, Plaintiff further states that “[t]hese representations were made in uniform promotional materials and product labeling.” ECF No. 1 ¶ 155. Because Plaintiff asserts that the alleged deceptive representations made to the women were within the confines of promotional materials explicitly approved as part of the PMA process, Plaintiff’s claims under the NYGBL cannot succeed. The MDA expressly preempts any state law that imposes a requirement that is in addition to or different from an FDA requirement. Plaintiff’s claims go to the heart of express preemption because she asserts that the FDA-approved promotional materials should have been “different” and that is exactly what the MDA proscribes. *See Horowitz*, 613 F. Supp. 2d at 288 (“[U]sing the NYGBL to attack [an] FDA-approved label would run afoul of the MDA’s preemption provision.”).

Plaintiff also claims that “during the premarket approval process, it was reported to the FDA that the Filshie Clip System had a migration incidence of 0.13%.” ECF No. 1 ¶ 53, and that the press release announcing the purchase of “Femcare, Ltd.” claimed that the Filshie Clip system was “safer than electrocautery and the newer hysteroscopic devices.” ECF No. 1 ¶ 55. A claim cannot proceed on this basis under the NYGBL because neither of these statements are “consumer-oriented.” The first involves statements made to the FDA and the second involves statements made to investors regarding the acquisition of a business. Moreover, claims based on statements made to the FDA are essentially “Fraud-on-the-FDA” claims and are impliedly preempted under

*Buckman*. See *Buckman*, 531 U.S. at 348-51 (construing misstatements made in disclosure to the FDA as “fraud-on-the-FDA” claims and holding that such claims are impliedly pre-empted by federal law.)

Finally, Plaintiff states that she was “provided with a Disclosure and Consent for medical and surgical procedures which included generic risks and hazards associated with the procedure,” but that “no mention was made of the risk of migration and the appurtenant damages that could be caused by the Filshie Clips.” ECF No. 1 ¶ 62. However, this statement has nothing to do with the Filshie Clip, but instead relates only to the “surgical procedure” used to implant the Filshie Clip. *Id.* Accordingly, it cannot be the basis of a claim regarding false advertisement about the Filshie Clip. Moreover, Plaintiff fails to allege that the disclosure provided to her was authored by and provided by the Defendants. The Court may not infer from the mere allegation that Plaintiff was “provided” with a piece of paper at the time of surgery that Defendants she chose to sue were responsible for the words on that paper.

Plaintiff’s claims under the New York General Business Law must be dismissed.

## **II. Opportunity to Amend**

In her response to Defendants’ motion to dismiss, Plaintiff requests leave to replead her claims against Defendants. ECF No. 15 at 12 n.15. Plaintiff has not supplied the Court with any reason as to why such an amendment should be granted. Nevertheless, Federal Rule of Civil Procedure 15 instructs the court to “freely give leave [to amend] when justice so requires.” Fed. R. Civ. P. 15(a)(2). Leave to amend, however, may be denied if an amendment would be futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962). An amendment is considered futile if it could not withstand a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). See *Ricciuti v. N.Y.C. Transit Auth.*, 941 F.2d 119, 123 (2d Cir.1991).

Plaintiff's claims for design defect and failure to warn, in each case, under a strict liability and negligence cause of action, are each expressly preempted. Therefore, repleading those claims would be futile because there is no set of facts that Plaintiff could plead that would evade preemption. Accordingly, Plaintiff's request for leave to amend the design defect and failure to warn claims is denied.

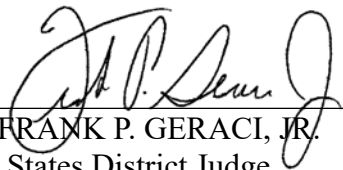
Plaintiff's request to replead her claims for manufacturing defect and violations of the New York Unfair Trade Practices Act is granted.

### **CONCLUSION**

For the foregoing reasons, Defendants' motions to dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(6), ECF Nos. 10, 20, 25, are GRANTED. Plaintiff's Complaint is DISMISSED with leave to file an amended complaint respecting her claims of a manufacturing defect and violations of New York Unfair Trade Practices Act.

IT IS SO ORDERED.

Dated: July 24, 2023  
Rochester, New York

  
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HON. FRANK P. GERACI, JR.  
United States District Judge  
Western District of New York